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SMITH MOORE LEATHERWOOD LLP			EXAMINER	
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			ART UNIT	PAPER NUMBER
			1618	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/563,747	Applicant(s) HARREN ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22, 24 - 27, 29 - 47, 50 - 61, 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 24 - 27, 29 - 47, 50 - 61, 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed October 29, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 37 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each claim recites the limitation "the composite" in line 1. There is insufficient antecedent basis for this limitation in the claim.

3. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the claim requires only a single polymer particle, as indicated by the article "an" at the beginning the claim or a plurality of particles because of the phrase "polymer particles" (lines 1 – 2).

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Claim Objections

4. Claims 24 and 26 are objected to because of the following informalities: the word "of" should not be present in front of the first item of the list. This extra "of" occurs in line 3 of claim 24 and line 4 of claim 26. Appropriate correction is required.

5. Claim 27 is objected to because of the following informalities: as currently phrase, it does not appear that a comma is required in the phrase "any one of selected from the following, an allantoin". "Any one of selected" is not grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 22, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (US 2003/0004479). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 29, 2008 and those set forth below. This rejection is no longer applied to canceled claims 23 and 38, whose limitations have been incorporated into independent claim 22.

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Applicant traverses this rejection on the grounds that the compositions of plant powder and water-absorbent resin, the plant powder serves as an odor control agent, not the combination of the water-absorbing polymer particles and a care substance, wound-treating substance or a care substance and a wound-treating substance. Further, it is preferred the plant powder be added to a superabsorbent polymer. The method of preparing the composition of Ueda et al. results in a mixture of the two powders, but not in water-absorbing particles in which an active substance is homogeneously distributed over the absorber mixture as required by the amended claim, a distribution which is only achieved by addition of the active substance to the monomer solution prior to or during the polymerization reaction.

These arguments are not found persuasive. Applicant has indicated in the specification that care substance can be a plant extract and that in another aspect of the invention care substances which have no deodorizing effect can be used (§ [0034] of the PGPub of the instant application). Ueda et al. utilizes extracts and essences as the active ingredient (§ [0006] of Ueda et al) and deodorizing compounds can be “care substances”. The claims of the instant application are not limited in such a way as to exclude the use of super-absorbent polymer material as the absorber matrix. Even if the claims were limited to non-super-absorbent polymer material, “the prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). **MPEP 2123**. The Examiner was unable to locate any

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reference in Ueda et al. which expressed a preference for a super-absorbent material although in the absence of a definition of what defines a super-absorbent material, such a preference may be present and the Examiner could not identify that information.

Addition of the active substance prior to or during the polymerization process will result in a final product in which the active substance is homogeneously distributed within or throughout the polymeric mixture. However, the claims recite that the “active substance is homogeneously distributed over the absorber matrix”. In this context, “over” can mean a layer of absorber matrix material, previously polymerized, which is then coated with the active substance - the active substances is present in a layer over the matrix material, and is not contained within the matrix itself. Also, the limitation of “over the absorber matrix” could be interpreted as that there is no active substance entrapped with the polymeric matrix itself but rather is applied to the surface of the polymer. Therefore, alternative methods exist that result in a homogenous distribution of the active substance over, but not within, besides incorporation of the active substance prior to or during polymerization exist. The product produced by Ueda et al. results in a homogenous distribution over the absorber matrix particles.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 22 and 45 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 29, 2008 and those set forth herein.

Applicant traverses this rejection on the same grounds discussed above.

This rejection is maintained for the same reasons discussed in greater detail above.

12. Claims 22 and 45 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of Chmelir et al (US 6,552,141). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 29, 2008 and those set forth below.

Applicant traverses this rejection on the grounds the Chmelir et al. is completely silent about any combination of the water-absorbing polymers with any care or wound-treating substances and is silent in regards to addition of the active ingredient to the monomer solution or to the gel which would lead to a homogeneous distribution of the active substance over the absorber matrix.

These arguments are not found to be persuasive. As discussed in greater detail above regarding the Ueda et al. reference, addition of the active ingredient to the monomer solution is not the only way to homogenously apply the active substance to the absorber matrix.

13. Claims 22, 24 – 27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Champ et al. (DE 10257002) in view of Ueda et al. (US 2003/0004479). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 29, 2008 and those set forth below. (Note: In addition to the machine translation previously provided for Champ et al., a non-machine translation of this document is included with this Office Action).

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Applicant traverses this rejection on the grounds that Champ et al. discloses to treat the surface of foamed hydrogels, after having been dried, with a dispersion of a skin care agent, which does not lead to a homogenous distribution of the skin care agent in the foamed hydrogel as it only penetrates the surface region of the dried composition. Even if one skilled in the art would combine these references, he would have brought into contact the polymer particles of Ueda et al. with a dispersion of skin care agent, obtaining particles in which the skin care agent is only distributed on the surface of the particles, but not homogeneously distributed as required by amended claim 21.

These arguments are not found to be persuasive. The skin care agent of Champ et al. can be applied by a number of methods, such as spraying or dipping the foamed materials into a solution of the skin care product which impregnates the hydrogel with active substance and the solvent is removed (p 4, ¶ 2 of the machine translation). These materials are designed to absorb solutions and are in a dry state prior to application of the skin care product. As the solution of skin care product will also be absorbed by the absorber matrix, any area of the matrix moistened during the impregnation process will be homogeneously with the skin care product. While the reference reports the final concentration of the skin care product at the surface, as discussed previously any part of the product moistened during the application of the skin care product would be homogeneously coatings, and particularly if the dipping method used, the entire mass of the absorber matrix would be homogeneously coated with skin care agent and the homogeneously distribution over the absorber matrix claim limitation is met.

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14. Claims 22, 24 – 27, 29 – 40, 43 – 47, 50 – 57, 59 – 61 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Champ et al. (DE 10257002) and Ueda et al. (US 2003/0004479) as applied to claims 22, 24 – 27, 29 – 30 and 69 above, and further in view of and Kenndoff et al. (US 5,844,013).

Applicant traverse the rejection over these same references, previously applied to claims 31, 36, 50 and 54, that one studying the disclosure of Kenndoff et al. would incorporate any active substance in the polyurethane gel, but certainly not in the particulate-water absorbing polymer. In combining the teachings of these references, a person skilled in the art would arrive at a polyurethane gel matrix comprising a particulate water-absorbing polymer, wherein the active substance is incorporated in the polyurethane matrix, not in the particulate water-absorbing polymer.

The Examiner was unable to locate in the Kenndoff et al. any teaching regarding the inclusion of care and/or wound-treating substance being incorporated into the product. A non-aqueous foaming agent, and optional polymerization catalysts or accelerators, fillers and additives can be included (col 4, ln 60 – col 5, ln 21). The compounds disclosed as those known in the polyurethane chemistry do not read on care and/or wound-treating substances, as best the Examiner can determine. Champ et al. and Ueda et al. disclose the addition of skin care agents or plant extracts to the water-absorbing particles, which would then be incorporated into the wound-dressing material taught by Kenndoff et al. Given the clear teachings of Champ et al. and Ueda et al. and the failure to include skin and/or wound-treating substances in the

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polyurethane matrix, one of ordinary skill in the art would not add the active substance to the polyurethane matrix, but would include it in the water-absorbent particles.

Because of the new product-by-process limitation added to independent claims 31, 50 and 69, the teachings of the references and how they apply to this new limitation are laid out below.

Champ et al. and Ueda et al. disclose a hydrogel material impregnated with a skin care agent, which can take the form of particles so that the particles are composed of an active substance and absorber matrix. These materials can be made in hygiene articles such as sanitary napkins.

Neither reference discloses the embedding of the water-absorbing matrix and active agent particles in a polycondensate polymer matrix.

Kenndoff et al. discloses a process of preparing a wound dressing material which comprises a polyurethane sheet backing, which reads on film, and a polyurethane gel foam which comprises a polyurethane gel, a water-absorbing material (abstract). The water-absorbing material is preferably a finely ground powder with a most preferable particle size 1 to 70 μm (col 7, ln 47 – 54). The water-absorbing material can be made from polyacrylates and copolymers thereof, in particular the sodium or potassium salts (col 7, ln 21 – 29). As shown in the examples (commencing at col 21, ln 1), the monomers which react to form the polyurethane (the polyol and diisocyanate) are combined with the superabsorber (water-absorbent component) which react to form a foam. This results in a composite material in which the water-absorbent particles are embedded in the polyurethane matrix. In example 1, the final material had an absorption

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capacity of 25 g of water per gram of material (col 21, ln 24). The backing (film layer) are generally flexible polyurethanes that are impermeable to water but permeable to water vapor (col 20, ln 1 – 5).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare the active agent and water-absorbing hydrogel particles taught by Champ et al. and Ueda et al. and to embed them in a polycondensate polymer matrix, as taught by Kenndoff et al. The instant claims are product claims and therefore these limitations are product-by-process limitations. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. Both the process of the instant claims and the cited prior art results in active agent and water-absorbing hydrogel particles surrounded by a polycondensate polymer matrix. The final materials can be used to prepare hygiene articles as taught by Ueda et al. and Champ et al. or a wound treatment article, as taught by Kenndoff et al.

15. Claims 22, 24 – 27, 29 – 47, 50 – 61 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Champ et al., Ueda et al. and Kenndoff et al. as applied to

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claims 22, 24 – 27, 29 – 40, 43 – 47, 50 – 57, 59 – 61 and 69 above and further in view of Morman et al. (US 5,883,028).

As discussed above, Champ et al., Ueda et al. and Kenndoff et al. disclose active substance-doped water absorbing polymer particles which can be embedded into a polyurethane matrix and film layer which is water impermeable, water-vapor permeable can be applied to the hygiene or wound treatment article.

None of the references provide a numerical value for the desired water vapor permeability of the film.

Morman et al. discloses a breathable elastic laminate particularly useful as an outer cover for disposable diapers and other personal care disposable products (col 1, ln 5 – 10). Good water vapor transmission makes the products more comfortable for the wearer (col 26 – 32). Suitable polycondensate polymer materials include polyurethanes (col 2, ln 1 – 5; example 3, col 13) and polyether esters (col 2, ln 1 – 5, example 2, col 13). The moisture vapor transmission rate (water vapor permeability) of the polymer layer should be at least $300 \text{ g/m}^2\text{-24 hours}$ (col 6, ln 13 – 18). The polymer films described by Morman et al. are highly permeable water but have a low permeability to ammonia and other odor-causing materials (col 1, ln 51 – 52), to allow for comfort while wearing by allowing for transmission of water vapor while reducing odors associated with ammonia in urine and other odor-causing substances.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare the hygiene or wound treatment article comprising active substance-doped water-absorbing polymer particles embedded in a polyurethane matrix

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with a polyurethane backing sheet as disclosed by Champ et al., Ueda et al. and Kenndoff et al. and to use a backing material with a water vapor permeability of the polymer layer should be at least $300 \text{ g/m}^2\text{-24 hours}$, disclosed by Morman et al. as an appropriate physical property for films used in the such products.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW